

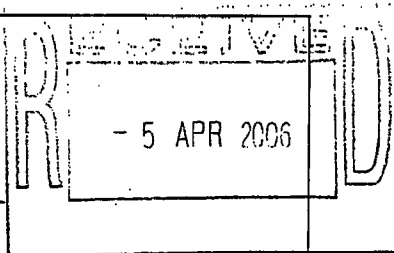
PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

BLAKEY, Alison
PROSIDION LIMITED
Windrush Court
Watlington Road
Oxford, Oxfordshire OX46LT



NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing
(day/month/year)

03.04.2006

Applicant's or agent's file reference
NC10009WO

IMPORTANT NOTIFICATION

International application No.
PCT/GB2004/050046

International filing date (day/month/year)
23.12.2004

Priority date (day/month/year)
24.12.2003

Applicant
PROSIDION LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | | | |
|--|--|--|--|--|
| Applicant's or agent's file reference NC10009/WO | | FOR FURTHER ACTION | | See Form PCT/PEA416 |
| International application No. PCT/GB2004/050046 | | International filing date (day/month/year) 23.12.2004 | | Priority date (day/month/year) 24.12.2003 |
| International Patent Classification (IPC) or national classification and IPC INV. C07D413/04 C07D413/06 C07D413/12 A61K31/4245 | | | | |
| Applicant PROSIDION LIMITED et al. | | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 5 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input checked="" type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | | |
| Date of submission of the demand 24.10.2005 | | Date of completion of this report 03.04.2006 | | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized officer Samsam Bakhtiary, M Telephone No. +49 89 2399-8556  | | |

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

10/584025

International application No.
PCT/GB2004/050046

1AP20 Rec'd PCT/PTO 22 JUN 2006

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-63 as originally filed

Claims, Numbers

1-16 received on 28.10.2005 with letter of 24.10.2005

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
 4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/050046

Box No. II Priority

1. ☒ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☒ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
 - ☒ claims Nos. 12-16
- because:
- ☒ the said international application, or the said claims Nos. 12-16 only with regard of industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):
see separate sheet
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☐ no international search report has been established for the said claims Nos.
 - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form
 - ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form
 - ☐ has not been furnished
 - ☐ does not comply with the standard
 - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
 - ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/050046

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-------|
| Novelty (N) | Yes: Claims | 1-16 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-16 |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | 1-11 |
| | No: Claims | 12-16 |

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

WAP20 Rec'd PCT/PTO 22 JUN 2006

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 12-16 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).
2. The initial phase of the search revealed a very large number of documents relevant to the issue of novelty. So many documents were retrieved that it is impossible to determine which parts of the claim(s) may be said to define subject-matter for which protection might legitimately be sought (Article 6 PCT). For these reasons, a meaningful search over the whole breadth of the claim(s) is impossible. Consequently, the search has been restricted to:

The compounds given in Formula I of claim 1, where:

- V is the formula of claim 2, W = N; X and Y are N or O
- A is $(CH_2)_n$, $n=0$

The amendments made namely introducing features of claims 2,3, 4,7 and 8 into claim 1 and introducing the preferred embodiments where A is $(CH_2)_n$, $n=0$ (see description page 3, line 43 and page 5, line 43), leads that this limited scope has been searched.

Claim 10 seems to correspond to original claim 17.

No added subject matter seems to occur.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/GB2004/050046

- D1: WO 98/17652 A (BOEHRINGER INGELHEIM PHARMA KG; BOEHRINGER INGELHEIM INTERNATIONAL GMB) 30 April 1998 (1998-04-30)
- D2: WO 01/12627 A (NPS PHARMACEUTICALS, INC; VAN WAGENEN, BRADFORD, C; STORMANN, THOMAS,) 22 February 2001 (2001-02-22)
- D3: WO 02/068417 A (NPS PHARMACEUTICALS, INC; SLASSI, ABDELMALIK; VAN WAGENEN, BRADFORD; S) 6 September 2002 (2002-09-06)
- D4: US-B1-6 239 160 (TIEBES JOERG ET AL) 29 May 2001 (2001-05-29)
- D5: WILLIAMS J P ET AL: "A solution-phase combinatorial synthesis of selective dopamine D4 ligands" COMBINATORIAL CHEMISTRY AND HIGH THROUGHPUT SCREENING, HILVERSUM, NL, vol. 3, no. 1, February 2000 (2000-02), pages 43-50, XP002280990 ISSN: 1386-2073
- D6: WO 00/24735 A (DOW AGROSCIENCES LLC) 4 May 2000 (2000-05-04)
- D7: WO 00/35913 A (AVENTIS CROPSCIENCE GMBH) 22 June 2000 (2000-06-22)
- D8: WO 97/46556 A (MERCK & CO., INC; BIFTU, TESFAYE; FENG, DANQING, DENNIS; FISHER, MICHA) 11 December 1997 (1997-12-11)
- D9: WO 2004/060362 A (MILLENNIUM PHARMACEUTICALS, INC; SCARBOROUGH, ROBERT, M; PANDEY, ANJAL) 22 July 2004 (2004-07-22)

2. Novelty

The claimed subject matter of this application is concerned with derivatives useful against satiety or obesity or diabetes.

The documents D3-D7 (see search report for appropriate location of in document) disclose specific compounds that do not affect novelty of the claimed subject matter.

We agree with the analysis made by the Applicant, indeed by limiting $n=2$ or 3 in claim 1, novelty is restored.

These compounds do not have the same activity as those of this application, therefore are only relevant against novelty.

3. Inventive step

Documents D1 and D2 disclose compounds having different pharmaceutical activities, namely the usefulness against neurodegenerative disorders such as diabetic neuropathic disorders (D1, page 66, line 17-page 67, line 1; D2, page 5, lines 19-22).

The closest prior art may be considered as being D8, which disclose compounds useful for the treatment of diabetes and/or obesity.

The problem to be solved by this application would be to provide novel derivatives useful against diabetes and/or obesity.

In view of the drastic structural differences from the compounds of D8 and those claimed in this application, the skilled man would not obviously derive to the claimed subject matter.

Re Item VI

Certain documents cited

Document D9, cited a PX in the search report may become relevant if this application is further proceeded in european phase.

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D7, D9 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

For the assessment of the present claims 12-16 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.